

§ 1311.130

(1) A hard token or any other authentication factor required by the two-factor authentication protocol is lost, stolen, or compromised. Such access must be terminated immediately upon receiving notification from the individual practitioner.

(2) The individual practitioner's DEA registration expires, unless the registration has been renewed.

(3) The individual practitioner's DEA registration is terminated, revoked, or suspended.

(4) The individual practitioner is no longer authorized to use the electronic prescription application (e.g., when the individual practitioner leaves the practice).

§ 1311.130 Requirements for establishing logical access control—Institutional practitioner.

(a) The entity within an institutional practitioner that conducts the identity proofing under § 1311.110 must develop a list of individual practitioners who are permitted to use the institutional practitioner's electronic prescription application to indicate that controlled substances prescriptions are ready to be signed and to sign controlled substance prescriptions. The list must be approved by two individuals.

(b) After the list is approved, it must be sent to a separate entity within the institutional practitioner that enters permissions for logical access controls into the application. The institutional practitioner must authorize at least two individuals or a role filled by at least two individuals to enter the logical access control data. One individual in the separate entity must authenticate to the application and enter the data to grant permissions to individual practitioners to indicate that controlled substances prescriptions are ready to be signed and to sign controlled substance prescriptions. A second individual must authenticate to the application to execute the logical access controls.

(c) The institutional practitioner must retain a record of the individuals or roles that are authorized to conduct identity proofing and logical access control data entry and execution.

(d) Permission to indicate that controlled substances prescriptions are

21 CFR Ch. II (4–1–11 Edition)

ready to be signed and to sign controlled substance prescriptions must be revoked whenever any of the following occurs, on the date the occurrence is discovered:

(1) An individual practitioner's hard token or any other authentication factor required by the practitioner's two-factor authentication protocol is lost, stolen, or compromised. Such access must be terminated immediately upon receiving notification from the individual practitioner.

(2) The institutional practitioner's or, where applicable, individual practitioner's DEA registration expires, unless the registration has been renewed.

(3) The institutional practitioner's or, where applicable, individual practitioner's DEA registration is terminated, revoked, or suspended.

(4) An individual practitioner is no longer authorized to use the institutional practitioner's electronic prescription application (e.g., when the individual practitioner is no longer associated with the institutional practitioner.)

§ 1311.135 Requirements for creating a controlled substance prescription.

(a) The electronic prescription application may allow the registrant or his agent to enter data for a controlled substance prescription, provided that only the registrant may sign the prescription in accordance with §§ 1311.120(b)(11) and 1311.140.

(b) If a practitioner holds multiple DEA registrations, the practitioner or his agent must select the appropriate registration number for the prescription being issued in accordance with the requirements of § 1301.12 of this chapter.

(c) If required by State law, a supervisor's name and DEA number may be listed on a prescription, provided the prescription clearly indicates who is the supervisor and who is the prescribing practitioner.

§ 1311.140 Requirements for signing a controlled substance prescription.

(a) For a practitioner to sign an electronic prescription for a controlled substance the following must occur: